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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/827,110 | 04/05/2001 | Elizabeth A. Wang | CIBT-P03-031 | 7778 |

28120 7590 10/02/2002

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BOSTON, MA 02110-2624

EXAMINER

TELLER, ROY R

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1653

DATE MAILED: 10/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/827,110

Applicant(s)

WANG, ELIZABETH A.

Examiner

Roy Teller

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-68 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I, claims 1-62, drawn to a method of modulating cell growth by administering a hedgehog or ptc therapeutic are for example classified in class 514, subclass 20.

a. A hedgehog therapeutic- claims 17-38

b. A ptc therapeutic- claims 39-55

Group II, claims 63-68, drawn to a product comprising a hedgehog polypeptide, are for example classified in class 530, subclass 333.

In addition to the election of group I or II, election under 35 U.S.C. 101 to one of the following is required for group I or II.

Claims 26-28 and 30-33, select one:

1) One patentably distinct and independent amino acid sequence from among SEQ ID NO: 9, 10, 11, 12, 13, 14, 15, 16 or Sonic, Indian, or Desert hedgehog, class 530, subclass 300

Claim 29, select one:

1) One patentably distinct and independent sequence from among SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, or 8, class 536, subclass 26.1.

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Claims 49, select one:

1) One patentably distinct and independent antisense oligonucleotide from among :

5'-GTCCTGGCGCCGCGCCGCGCGTCGCC;

5'-TTCCGATGACCGGCCTTTCGCGGTGA; and

5'- GTGCACGGAAAGGTGCAGGCCACACT

class 536, subclass 24.5

Claim 53, select one from each group: R1 group, R2 group, R3 group.

All are patentably distinct due to the different structures of each. Each species would require a different structure search.

The inventions are distinct, each from the other for the following reasons:

Inventions in group I and group II are distinct and/or independent, one from the other because the method of modulating cell growth does not require the product.

The amino acid sequences, nucleotide sequences, antisense oligonucleotides, and chemical structures are distinct and different on the basis of physical, chemical and biological properties, they are all of different function. The search of the patent and technical literature for one of the amino acid sequences, nucleotide sequences, antisense oligonucleotides, and chemical structures would not have resulted in a complete search for any one of the combinations.

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Because these inventions are distinct for the reasons given above and since they have acquired a separate status in the art as shown by their different classification and/or divergent subject matter, and/or are separately and independently searched, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirements be traversed (37 CFR 1.143).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (703) 305-4243. The examiner can normally be reached on Monday-Friday from 6:00 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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RT

Christopher S. F. Low
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600